

REMARKS

Entry of this amendment is respectfully requested.

It is believed the objections to the claims have been overcome by the amendments thereto.

The Examiner has not considered FR 2,713,487 and DE 2,547,696 cited in the IDS of February 6, 2004 because there was no concise explanation of the relevance of these documents. These references were cited in the International Search Report, and the indication of relevance is provided therein, and MPEP § 609 III A(3), reads as follows:

"[w]here the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report."

In view of the foregoing, it is respectfully requested that these references be considered and made of record.

Claims 15, 19 and 20 were rejected under §112, second paragraph, for failing to indicate an upper limit of the xenogenic substance to be administered. This rejection is respectfully traversed.

The active agent is applied, e.g., preferably in dry powder form to the lips. One would administer so much of the preparation as is sensibly possible to achieve the desired effect. In view of the foregoing, withdrawal of this rejection is respectfully requested.

Claims 15 and 20 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

The medicament of the invention quite simply is made of an RNA preparation obtained from a xenogenic organism, i.e., from an organism different than that to be treated. From the definition given at page 2, line 25 et seq. of the present specification, preferably naturally occurring RNA is used, and these are preferably not subjected to any chemical modification whatsoever but obtained directly from the respective organisms, e.g., other animals such as cattle, plants and monocellular organisms. The examples generally describe recovery from a yeast, but the specification clearly sets forth a broad range of sources as contemplated and described in the specification.

With respect to the Herpesviridae family, it is a relatively small family consisting of Herpes simplex and Herpes genitalis, and, although these herpes viruses can cause so different diseases, the same herpes viruses are concerned. A declaration will be provided along with two test reports using Herpes labialis (HSV 1) and Herpes genitalis (HSV 2) which clearly support the claimed effects of the invention. Clearly, this family is described in the present application, as are the xenogenic oligo-and/or polynucleotides.

With respect to skin tumors, basaliomas are provided as a species of tumor which may be treated in accordance with the present invention, but one skilled in the art would understand that this is intended to include other skin tumors treatable by the claimed methods.

The invention works with RNA obtained from the xenogenic tissues according to the methods given, and no separation of the obtained products according to any structural properties is necessary to obtain a preparation having the given properties. The simple nature of the invention is an asset, and is adequately described for the provisions of 35 U.S.C. § 112, first paragraph. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 15 and 20 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Draper. This rejection is respectfully traversed.

Draper concerns the use of ribozymes capable of specifically cleaving genomic RNA for treating viruses. This is something fundamentally different than the use of the xenogenic oligo- and/or polyribonucleotides according to the presently claimed invention. With preparations according to the invention, no ribozymes are present, and Draper supports this. On page 79, from line 25, Draper describes that the ribozymes according to his invention can be obtained by gene transcription or chemical synthesis.

The RNA used according to the present invention is preferably obtained neither by chemical synthesis nor by gene transcription but by simple extraction from the respective xenogenic cells. Ribozymes as use by Draper are enzymatically active RNA-containing molecules capable of specifically hydrolyzing genomic RNA, mRNA or hnRNA encoded by viruses. Naturally occurring ribozymes are RNA molecules capable of catalytically processing themselves, i.e., solely by themselves. Therefore, they are not capable of reacting and/or hydrolyzing other molecules or substrates. Therefore, Draper clearly teaches the use of non-naturally occurring ribozymes designed by molecular biology processes. They consist of target sequence-depending RNA sections at the 5'- and 3'- terminus of the artificial ribozyme and a central domain bringing about catalytic activity. These non-naturally occurring RNA constructs can be inserted in corresponding transcription vectors. Draper further teaches the production of the artificial ribozymes by expressing such transcription vectors in a bacterial or eukaryotic cell, cf. page 80, lines 4-8.

Artificial, non-naturally occurring RNA molecules such as the ribozymes of Draper cannot be referred to as xenogenic, not even when cell systems are used for producing them.

Originating from a particular target organism is understood by the skilled person only to mean that corresponding RNAs encoded by the genotype were not only produced in an organism but also stem from said organism evolutionarily. In other words, ribozymes as taught by Draper are not "xenogenic oligo- and/or ribonucleoties".

Claims 15 and 20 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Dirheimer. Applicants respectfully traverse. Applicants respectfully traverse.

Dirheimer does not disclose that the composition is applied once per recurrence, therefore, each and every limitation of the claim is not disclosed or suggested.

In view of the foregoing, allowance is respectfully requested.

If any additional fees are due to enter this amendment or to maintain pendency of this application, please charge the fees to Deposit Account No. 50-0624.

Respectfully submitted

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